

Commissioner of Patents
USSN 10/661,403

REMARKS

Claims 44 and 45 are pending in the application. Claims 1-43 have been cancelled previously.

Claim rejections - 35 U.S.C. § 112

Claims 44 and 45 have been rejected under 35 U.S.C. § 112, first paragraph. The Examiner states the specification, while being enabling for treatment of viral infections, does not reasonably provide enablement for prophylaxis. The Applicants respectfully submit that claims 44 and 45 now on file have been restricted to a method for the treatment of specific viral infection comprising administering a formulation comprising SEQ ID NOs: 22 or 24. In view of amendments presented hereinabove, reconsideration of the Examiner's rejection is respectfully requested.

Claims 44 and 45 have been rejected under 35 U.S.C. § 112, first paragraph. The Examiner mentions that the specification, while being enabling for treatment of HCV, HBV, Influenza A, RSV, HSV-1, HSV-2 and Ebola does not enable the treatment for infection caused by herpesviridae, hepnaviridae, filoviridae, flaviridae, orthomyxoviridae and paramyxoviridae. More specifically, the Examiner recognized that the data presented in the Declaration of Dr. Jean-Marc Juteau, and in the description, is enabling for the treatment of viral infection caused by HCV, HBV, Influenza A, RSV, HSV-1, HSV-2 and Ebola using REP 2031, and caused by HCV, HBV and HSV-1 using REP 2055. Further, the Examiner also mentions that no examples are provided for the treatment a viral infection caused by CMV using either REP 2031 or REP 2055. In this regard, the Applicants wish to respectfully point out that claim 44 has been amended to encompass a method for the treatment of a viral infection in a subject, comprising administering a therapeutically effective amount of at least one pharmacologically acceptable oligonucleotide formulation comprising SEQ ID NO: 22 having an antiviral activity, said viral infection being caused by a virus selected from the group consisting of HCV, HBV, Influenza A, RSV, HSV-1, HSV-2, Ebola and CMV, wherein said antiviral activity of said oligonucleotide occurs principally by a sequence independent mode of action. Further, claim 45 has been amended to encompass a method for the treatment of a viral infection in a subject, comprising administering a therapeutically

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effective amount of at least one pharmacologically acceptable oligonucleotide formulation comprising SEQ ID NO: 24 having an antiviral activity, said viral infection being caused by a virus selected from the group consisting of HCV, HBV and HSV-1, wherein said antiviral activity of said oligonucleotide occurs principally by a sequence independent mode of action.

The viral infection encompassed by the new claims now on file are restricted to infection caused by specific virus which the Examiner has acknowledged that there is exemplifying support in the description and in the Declaration filed previously. The Applicants also wish to point out that contrary to the Examiner affirmation, the Applicants have provided enabling data for treatment of a viral infection caused by CMV using REP 2031. The Applicants first submit that in the Declaration of Dr. Jean-Marc Juteau filed August 11, 2006, the following Table 6 was submitted presenting data demonstrating the efficacy of REP 2031 (SEQ ID NO: 22) to inhibit systemic CMV infection:

Table 6
ONs are effective agents against systemic CMV infection

| ON dose | Liver titer (log10/ml tissue) |
|----------------------|-------------------------------|
| 0 (placebo control) | 2.9 |
| 20mg/kg/day REP 2006 | 1.1 |
| 20mg/kg/day REP 2031 | 0.7 |
| 20mg/kg/day REP 2107 | 0.9 |

Secondly, in the Declaration of Dr. Jean-Marc Juteau filed June 21, 2007, the following Figure 3 was submitted disclosing the efficacy of REP 2031 (SEQ ID NO: 22) to inhibit CMV liver replication *in vivo*:

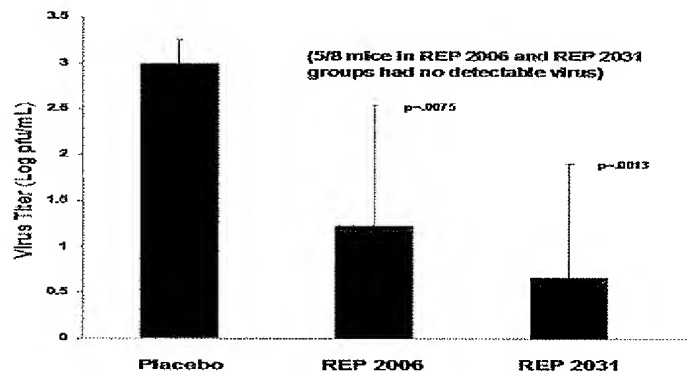


Figure 3. IP administration of either REP 2006 or REP 2031 (SEQ ID NO: 22) significantly inhibits CMV liver replication *in vivo*.

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Consequently, the Applicants clearly demonstrated the efficacy activity of SEQ ID NO: 22 to inhibit CMV infection now claimed, and thus a person skilled in the art is able to fully predict possible results of the clinical benefit of the claimed method only based on these results.

In view of arguments and amendments presented hereinabove, reconsideration of the Examiner's rejection is respectfully requested..

Double Patenting

The Examiner rejected claims 44 and 45 on the ground of nonstatutory double-patenting over claims 1, 2, 14, 15, 17, 18, 21, 22, 27-29 and 39-42 of copending Application No. 10/661,097.

In this matter, the Applicants submit that this rejection should now be moot in light of the Terminal Disclaimer under 37 C.F.R. §1.321 enclosed herewith.

In view of the foregoing, Applicants respectfully request that the double-patenting rejections be withdrawn.

It is submitted, therefore, that new claims 44 and 45 are in condition for allowance. Reconsideration of the Examiner's rejections is respectfully requested. Allowance of claims 44 and 45 at an early date is solicited.

No additional fees are believed to be necessitated by this amendment. Should this be in error, authorization is hereby given to charge Deposit Account No. 19-5113 for any underpayment or to credit any overpayment.

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In the event that there are any questions concerning this amendment or the application in general, the Examiner is respectfully urged to telephone the undersigned so that prosecution of this application can be expedited.

Respectfully,

Date: September 14, 2007

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Enc. Terminal disclaimer